

## DRIB No. 02 December 2007

## **DRUG RESEARCH INFORMATION BULLETIN**

## Calculate Amount of Aquaflor® (florfenicol, 50%) to Add to Fish Feed

Daniel Carty, James D. Bowker, Molly P. Bowman, and David A. Erdahl

U.S. Fish and Wildlife Service, Aquatic Animal Drug Approval Partnership Program 4050 Bridger Canyon Road, Bozeman, Montana 59715, U

Aquaflor<sup>®</sup> Type A medicated article (Aquaflor<sup>®</sup>; Schering-Plough Animal Health Corporation, Summit, NJ) is 50% active florfenicol, a broad-spectrum antibiotic with both bacteriostatic and bacteriocidal properties. Florfenicol is active against a variety of Gram-positive and Gram-negative bacteria.

In October, 2005, the U.S. Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) approved Aquaflor® for use to control mortality in catfish due to enteric septicemia associated with *Edwardsiella ictaluri* (New Animal Drug Application [NADA] 141-246). In March, 2007, FDA/CVM approved Aquaflor® for use to control mortality in freshwater-reared salmonids due to coldwater disease associated with *Flavobacterium psychrophilum*. Under NADA 141-126, Aquaflor® is administered at a dose of 10 mg florfenicol/kg fish/day for 10 consecutive days and can only be used with a Veterinary Feed Directive.

Current Aquaflor® efficacy research is focused on expanding the product's label claim(s). Much of this work is conducted under Investigational New Animal Drug (INAD) exemption Florfenciol INAD 10-697, which is administered by the U.S. Fish and Wildlife Service (FWS) Aquatic Animal Drug Approval Partnership (AADAP) program. The FWS INAD allows Aquaflor<sup>®</sup> to be used on a variety of fishes in a variety of experimental and production settings to generate efficacy data needed to support FDA/CVM approval of the following indications: (1) control of mortality in freshwater-reared salmonids due to furunculosis; (2) control of mortality in freshwater-reared salmonids and catfish due to systemic columnaris disease; and (3) control of mortality in tilapia and hybrid striped bass due to Streptococcus iniae. For indications (1) and (2), the dose is 10 mg florfenicol/kg fish/day for 10 consecutive days. For indication (3), the dose may be increased to 15 mg florfenicol/kg fish/day for 10 consecutive days.

Under INAD 10-697, Aquaflor<sup>®</sup>-medicated feed can be purchased directly from a licensed feed mill or Aquaflor<sup>®</sup> may be obtained and added to feed by hatchery personnel. We note that that post-approval, where indicated, top-dressed medicated feed

will need to be sourced from a feed mill licensed to make medicated feeds.

Intended feeding rate must be taken into account when ordering or preparing Aquaflor®-medicated feed to ensure that the dose administered is 10 mg florfenicol/kg fish/day. For this dose, AADAP has developed a reference table for easily determining the amount (g) of Aquaflor® to add to a 20-kg or 50-lb bag of feed when fish are fed at 0.5 – 5.0% body weight (% BW) in 0.5% increments or are fed at 10% BW (Table 1). However, it is not obvious how to calculate amount of Aquaflor® to add to feed for %BWs not listed in Table 1.

In this bulletin, we describe the mathematical relation between %BW and percent Aquaflor<sup>®</sup> (%AQ) to add to feed *and* explain how to calculate amount of Aquaflor<sup>®</sup> to add to a specific amount of feed to achieve a dose of 10 mg florfenicol/kg fish/day when fish are fed at any %BW between 0.5 and 10% (as follows):

For a dose of 10 mg florfenicol/kg fish/day, the relation between %BW and %AQ is described by the equation (Figure 1),

$$%AQ = [(0.2001 \div %BW) - 0.0002].$$

Consequently, determining the amount (g) of Aquaflor<sup>®</sup> to add to a specific amount (g) of feed is a simple, three-step process:

- (1) Enter %BW into the equation, and calculate %AQ (e.g., If fish will be fed at 1.5% BW, the %AQ to add to feed =  $[(0.2001 \pm 1.5) 0.0002] = 0.133\%)$ ;
- (2) Convert %AQ to a decimal fraction (e.g.,  $0.133\% \div 100 = 0.00133$ ); and
- (3) Multiply the result by the amount (g) of treated feed to prepare (e.g.,  $[0.00133 \times 20,000 \text{ g feed}] = 26.60 \text{ g Aquaflor}^{\otimes}$  premix should be added to 20,000 g feed).

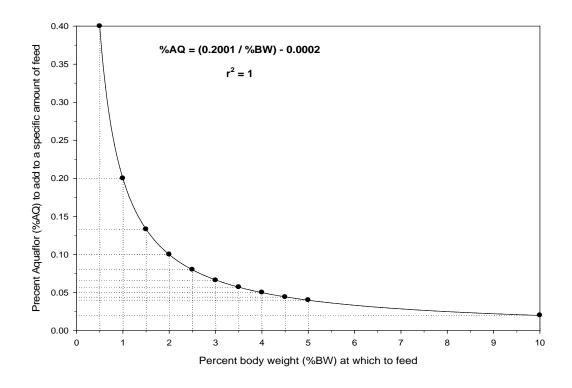


**Table 1.** To determine amount of Aquaflor<sup>®</sup> to add to either a 50-lb (22,680 g) or 20-kg (20,000 g) bag of fish feed, find the percent body weight (%BW) at which fish will be fed, go to the fourth or fifth row of the table, and read the amount (g) of Aquaflor<sup>®</sup> to add.<sup>a</sup>

%BW to feed	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	10.0
%AQ to add	0.40	0.200	0.133	0.100	0.080	0.066	0.057	0.050	0.044	0.040	0.020
Amount (g) of Aquaflor® to add to either a 50 lb or 20 kg bag of feed											
50 lb	90.7 2	45.36	30.16	22.68	18.14	14.97	12.93	11.34	9.98	9.07	4.54
20 kg	80.0	40.00	26.60	20.00	16.00	13.20	11.40	10.00	8.80	8.00	4.00

<sup>&</sup>lt;sup>a</sup>Amount (g) of Aquaflor<sup>®</sup> to add to a specific amount (g) of feed = [(amount (g) of feed to be treated)  $\times$  (percent Aquaflor<sup>®</sup> to add  $\div$  100)].

**Figure 1.** Relation between percent body weight (%BW) and percent Aquaflor<sup>®</sup> (%AQ) to add to fish feed to achieve a dose of 10 mg florfenicol/kg fish/day.



Aquaflor® is a registered trademark of Schering-Plough Animal Health Corporation, http://www.spah.com/usa/